

Exhibit 9

1 UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 IN RE: NATIONAL) MDL No. 2804
5 PRESCRIPTION OPIATE)
6 LITIGATION) Case No.
7) 1:17-MD-2804
8)
9 THIS DOCUMENT RELATES TO) Hon. Dan A.
10 ALL CASES) Polster
11)

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Tuesday, May 14, 2019

HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
CONFIDENTIALITY REVIEW

Videotaped Deposition of JAMES E.
RAFALSKI, VOLUME 2, held at Weitz &
Luxenburg PC, 3011 West Grand Avenue, Suite
2150, Detroit, Michigan, commencing at
8:25 a.m., on the above date, before
Michael E. Miller, Fellow of the Academy of
Professional Reporters, Registered Diplomate
Reporter, Certified Realtime Reporter and
Notary Public.

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1 here today, no, sir.

2 Q. Okay. So your report does not
3 identify any shipments by manufacturers to
4 distributors that you claim should have been
5 reported as suspicious?

6 A. My opinion goes to whether or
7 not there were effective -- or suspicious
8 orders, effective suspicious order systems in
9 place and/or the maintenance of effective
10 controls, the due diligence. I do not do any
11 calculations that would identify any specific
12 orders.

13 Q. Okay. So just to be clear, in
14 response to my question, your report does not
15 identify any shipments by manufacturers to
16 distributors that you claim should have been
17 reported as suspicious, correct?

18 A. I think there's some instances
19 in my report, there was -- there may be a
20 description of a relationship or some
21 transactions between a -- let me think a
22 second.

23 Q. Uh-huh.

24 A. Because I have all of the
25 different companies.

1 (Document review.)

2 A. I don't believe so, no, sir.

3 BY MR. O'CONNOR:

4 Q. Okay. And at trial, do you
5 intend to offer any opinion regarding whether
6 any particular order submitted to a
7 manufacturer was suspicious?

8 A. If I'm requested to do that
9 analysis by counsel, I guess that would be a
10 possibility. I haven't done the analysis as
11 today, so I couldn't offer that opinion.

12 Q. So as you sit here today, you
13 do not have an opinion on whether any
14 particular order that was shipped by a
15 manufacturer was suspicious?

16 A. I think I have an opinion.

17 Q. But you haven't identified any
18 order, correct?

19 A. I have not identified a
20 specific order, but I have an opinion on the
21 conduct.

22 Q. And are you offering any
23 opinion in this litigation that any
24 particular order that was shipped into Summit
25 or Cuyahoga Counties was suspicious?

1 A. Yes.

2 Q. Okay. And are you offering any
3 opinion in this litigation that any
4 particular order shipped by a manufacturer
5 into Summit or Cuyahoga County was
6 suspicious?

7 A. I'm sorry, shipped by a
8 manufacturer --

9 Q. Correct.

10 A. -- to a distributor?

11 Q. That's right. To -- to someone
12 in Cuyahoga or Summit County.

13 A. No, sir.

14 Q. Okay. With respect to a
15 manufacturer, what is a suspicious order?

16 A. Well, if a manufacturer has
17 conducted a sufficient due diligence or
18 onboarding process and they've evaluated the
19 scope of their customers' business and the
20 needs, they would establish a pattern, and
21 that pattern would give them an idea of
22 initially the volume of drugs they need to
23 purchase.

24 Now, if it's brand-new
25 customer -- yours is kind of a hypothetical.

1 If it's a brand-new customer, there's not a
2 pattern or a frequency, but they would start
3 out with what they assess as a legitimate
4 volume, and they would monitor that volume,
5 and if a customer exceeded that, that should
6 trigger as an unusual size.

7 But to give you just a general
8 definition, it's kind of a broad topic
9 because it depends on the scope of business
10 of the manufacturer, of the customer, the
11 type of products, the needs, so the -- prior
12 to ever shipping an order, the importance is
13 to understand what the legitimate needs is of
14 a customer.

15 Q. Yesterday you testified that it
16 was important to understand what a usual
17 order was so that you could determine what a
18 suspicious order was.

19 Do you generally recall that
20 testimony?

21 A. I think that's a general
22 description. I think we were discussing the
23 size, so I think before you would know an
24 unusual size, you would need to know the
25 usual size.

1 And I think that's kind of the
2 simpler way of what I just said, is that if
3 you don't really have a comprehension of what
4 is the legitimate needs of your customer,
5 then you couldn't know an unusual order --
6 unusual size of an order, I'm sorry.

7 Q. What information would you need
8 to determine what a usual order looked like
9 for a manufacturer?

10 MR. FULLER: Form.

11 THE WITNESS: I'm sorry, you
12 said something?

13 MR. FULLER: Object to form.

14 THE WITNESS: Oh. Sorry.

15 A. I think that's dependent on the
16 skill of your compliance employees. I think
17 you go in and evaluate the distributor. I
18 don't think the distributor would purchase a
19 manufacturer's product with an idea on how
20 they were going to sell it and market it, and
21 I think you would evaluate what their scope
22 of business is and the type of customers they
23 were; how many pharmacies they could
24 distribute to.

25 I think you'd have to get some

1 A. I can think of one.

2 BY MR. O'CONNOR:

3 Q. What was that?

4 A. I'm not sure I can discuss that
5 with the Touhy letter.

6 MR. FULLER: Not if it was
7 based on an investigation that you did
8 while an agent.

9 MR. O'CONNOR: Sorry, are you
10 not answering that question?

11 THE WITNESS: That's what I
12 stated, sir.

13 MR. O'CONNOR: Okay.

14 THE WITNESS: Because it's not
15 publicly readily available that
16 someone would know that.

17 BY MR. O'CONNOR:

18 Q. While we're talking about
19 Touhy, you have said and your counsel has
20 stated on a number of occasions yesterday and
21 today that you're not permitted to speak
22 about any particular investigation you were
23 involved in while at the DEA; is that fair?

24 A. That's not publicly or readily
25 available.

1 Q. Okay. And with respect to
2 Mallinckrodt in particular, given those
3 restrictions, is it fair to say that all of
4 the opinions you express in your report are
5 based on materials that you reviewed in
6 connection with this litigation?

7 A. Yes, sir.

8 Q. And your opinions are not based
9 on any other information outside of what
10 you've relayed and referred to in your
11 report?

12 A. Well, it's difficult to --
13 since I worked the case for a period of
14 years, obviously, that there may be things I
15 know that aren't part of the discovery, but
16 the opinion I wrote is only based on the
17 information contained in my report.

18 Q. Okay. And do you intend at
19 trial to offer any information or opinions
20 that are based on something other than what
21 you've cited here in this report?

22 MR. FULLER: Object to form,
23 based on the same basis earlier.

24 A. If the Touhy letter is in place
25 and it's restricted by the government, then I

1 would not offer anything outside of what's
2 contained in my report or currently contained
3 in the discovery material.

4 BY MR. O'CONNOR:

5 Q. In your report, do you express
6 any opinion as to the adequacy of
7 Mallinckrodt's present day suspicious order
8 monitoring program?

9 A. I do not believe I do.

10 Q. Okay. And just so we're clear
11 about the period of time your opinions do
12 relate to, do you have any opinion with
13 respect to Mallinckrodt's suspicious order
14 monitoring program in 2018?

15 A. I do not.

16 Q. 2017?

17 A. I don't think my report
18 references any time period after 2011.

19 Q. Okay. So fair to say in this
20 litigation, you're not providing any opinion
21 with respect to Mallinckrodt's suspicious
22 order monitoring program after 2011?

23 MR. FULLER: Form.

24 A. At the current time based --
25 I'm sorry.

1 MR. FULLER: Form. I just
2 objected to the form.

3 Go ahead.

4 A. Based on the report as it
5 stands right here without being amended, it
6 doesn't address any time periods that I can
7 find past 2011, so that would be an accurate
8 statement as of today.

9 BY MR. O'CONNOR:

10 Q. Do you plan to amend your
11 report to add opinions related to
12 Mallinckrodt's program after 2011?

13 A. If requested by counsel, I
14 will.

15 Q. Okay. As you sit here today,
16 do you have any opinions with respect to
17 Mallinckrodt's suspicious order monitoring
18 program after 2011?

19 A. No, I do not.

20 Q. Okay. And as you sit here
21 today, do you have any opinions with respect
22 to Mallinckrodt's DEA regulatory compliance
23 outside of suspicious order monitoring after
24 2011?

25 A. It doesn't appear in my report,

1 so I wouldn't comment on it.

2 Q. Okay. So you have no opinion
3 on that subject?

4 A. No, I think the Touhy would --
5 if I had an opinion or had knowledge and it's
6 not cited here or it's not a public
7 knowledge, I wouldn't make comment on it.

8 Q. Mr. Rafalski, would you agree
9 that it's possible to have a suspicious order
10 monitoring program in place without a formal
11 written policy?

12 A. In a hypothetical sense?

13 Q. Uh-huh.

14 A. Depending on the scope of
15 business, the size of the business and the
16 intended customers, I believe it could be
17 done manual -- manually, but that's
18 hypothetically based on those factors and
19 probably others.

20 Q. Okay. So just because a
21 company doesn't have a formal written policy
22 does not mean it didn't have a suspicious
23 order monitoring program, fair?

24 A. Hypothetically, that could
25 occur, yes, sir.

1 Q. Okay. And is it fair to say in
2 your -- in your opinion, Mallinckrodt's
3 suspicious order monitoring program during
4 the time period that you examined it involved
5 an algorithm?

6 A. Yes, sir.

7 Q. Okay. And your opinion is that
8 that algorithm-based program was not
9 adequate?

10 A. Yes, sir. And the reason why
11 is it used a multiplier, so anytime there's a
12 multiplier applied, if it's an effectively
13 designed system, you've established a
14 threshold for a customer that's their
15 legitimate use, to give that customer two or
16 three times more than that established
17 threshold I don't think is an effective
18 suspicious order system.

19 Q. Is it your understanding that
20 Mallinckrodt's suspicious order monitoring
21 program consisted solely of an algorithm?

22 A. That's my understanding in
23 reviewing records. It did not look at size
24 or pattern.

25 Q. Okay. So if Mallinckrodt's